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# Effect of tourniquet on skeletal muscle ischaemia and return of function: A prospective randomized clinical study

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#### Abstract

**Objectives:** The purpose of this prospective randomized trial was to examine the effect of tourniquet use on skeletal muscle damage and return of function after closed tibial interlocking nail.

**Methodology:** 74 patients who underwent closed tibial nailing were randomly allocated to the use of an inflated pneumatic tourniquet (group 1, n =37) or no tourniquet (group 2, n =37). Patients with Compound tibia fractures; Compartment syndrome; Multiple fractures; Polytrauma and infection were excluded. The primary outcome measures were pain, measured with a visual analog scale (VAS), return of activity measured by ability to do SLR(Straight Leg Raising) postoperatively and serum creatine phosphokinase (CPK) levels monitored preoperatively and 24 hours postoperatively.

**Results:** The 2 groups did not differ in baseline demographics. Mean duration of surgery was similar in both groups. There was threefold increase in mean CPK in group1when the duration of surgery is < 90 minutes and fivefold increase when duration exceeded 90 minutes, but only 2 times increase of CPK in group2 which was not affected by the duration of surgery. The difference in the mean scores between the two groups was statistically significant from 2nd to 4th postoperative day (P-value < 0.05). The mean days to regain SLR in patients with duration of surgery more than 90 minutes were significantly higher than that of mean scores in patients with duration of surgery less than 90 min in group1 only.

**Conclusions:** It is much safer not to use tourniquet where surgery is going to be prolonged than 90 minutes. Early postoperative pain is lesser and return of function is faster in patients who were operated without a tourniquet as compared to patients with prolonged surgery with tourniquet.

Keywords: Tourniquets, creatine phosphokinase, VAS, closed fractures

#### Introduction

A tourniquet is a constricting or compressing device used to control venous and arterial circulation to an extremity for some time. Operations on the extremities are made easier by the use of a tourniquet [1]. The tourniquet is a potentially dangerous instrument that must be used with proper knowledge and care [2]. In some procedures, a tourniquet is a luxury, whereas, in others, such as delicate operations on the hand, it is a necessity.

Tibia shaft fractures are commonly treated with closed reduction and internal fixation with an interlocking intramedullary nail. However, there is no consensus regarding the use of a tourniquet during intramedullary nailing for tibia fractures. There are lacunae in the existing literature regarding the degree of muscle damage occurring during intramedullary nailing of tibia fractures and its relation with the use of a tourniquet and the duration of surgery.

Many factors have been implicated in the development of post tourniquet complications but the duration of a tourniquet and tourniquet pressure is of the most importance. Two hours of tourniquet time is generally accepted as a safe duration for the human lower limb, however, experimental evidence to support this clinical aphorism is sparse [3].

Creatine phosphokinase (CPK) is an intracellular enzyme expressed by various tissues and cell types including muscles. Due to the relatively small molecular size of Creatine Phosphokinase (CPK), it leaks out of ischaemic muscle cells into the circulation. CPK catalyzes the conversion of creatine and consumes adenosine triphosphate (ATP) to create phosphocreatine (PCR) and adenosine diphosphate (ADP) [4].

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The release of intracellular enzymes to the extracellular space is considered by some to be the earliest reliable biochemical signs of ischaemic cellular damage to the muscles [5]. Walter Gail L, Smith Graham S [6], stated that "Increased serum activities of Creatine Phosphokinase (CPK), Aspartate Aminotransferase (AST), and lactate dehydrogenase (LDH) occur with a muscle injury. Of these three, CPK is generally the most sensitive, with peak activity reached within about 6-12 h following the insult. CPK has a relatively short half-life (about 2-4 h), and activity returns rapidly to a normal following cessation of myodegeneration or necrosis [6]. Oda J, Tanaka H et al. in analysed 372 patients with Crush syndrome caused by the Hanshin-Awaji earthquake and found that peak serum CPK concentration increased with the number of crushed extremities. They concluded that the degree of CPK elevation correlates with the degree of muscle injury [7].

Although, till date, most of studies have focused on the benefits of tourniquets in extremity surgery, their effect on post-operative rehabilitation remains sparsely studied [1, 2, 5]. This study aims to evaluate the tourniquet induced muscle injury in intramedullary nailing of tibial shaft fractures. Our primary hypothesis was that the use of a pneumatic tourniquet would result in delayed return to activities, as well as increased serum CPK values as tourniquet use is will cause muscle ischemia and weakness. Theoutcome variable of our study included postoperative pain and postoperative return of active straight leg raise (SLR). We analysed the association of these outcomes with the use of tourniquet, tourniquet time, duration of surgery, and the change in CPK levels. The purpose of this prospective randomized trial was to examine the effect of tourniquet use on rehabilitation, return to activities, and muscle damage.

# **Materials and Methods**

This institutional-based Randomized Prospective comparative study was conducted in the Department of Orthopaedics, tertiary care University teaching hospital after approval of the Institutional Ethics Committee. 80 patients with tibial shaft fractures were enrolled according to inclusion and exclusion criteria which are:

Inclusion Criteria: Adult patients (above 18 years of age); Closed tibia shaft fractures; Fit for Closed reduction and internal fixation with Intramedullary Interlocking Nailing.

Exclusion Criteria: Compound tibia fractures; Compartment syndrome; Multiple fractures other than the tibia fracture being managed operatively; Polytrauma; Patients suffering from ischaemic heart disease; Patients suffering from peripheral vascular disease; Patients suffering from sickle cell disease; Fractures being treated by open reduction and plate and screw fixation; Brain injury/stroke; Convulsions; Delirium tremens; Dermatomyositis or polymyositis; Electric shock; Myocarditis; Pulmonary infarction; Muscular dystrophies; Myopathy; Infection.

They were informed about the nature and objective of the study and written informed consent was taken before recruiting them into the study. Preoperative counselling & pre-operative anaesthetic assessment were done. Pre-operative radiographic assessment using plain radiographs of the involved leg in anteroposterior and lateral view was obtained. Six patients were excluded from the study as they required either and open reduction or additional injuries were detected later leaving 74 patients to be included in final study.

Venous blood samples were collected for assessment of Serum Total Creatine Phosphokinase (CPK) levels.

1st sample: 1 day before the surgery 2nd sample: 24 hours after the surgery

Anaesthesia: All surgeries were performed under spinal anaesthesia (subarachnoid block). No local or Epidural analgesia was given to any case.

**Randomization:** Patients included in the study were randomized into two groups using Alternate Allocation method as follows:

- 1. Group 1:- Intramedullary tibia nailing with the use of a tourniquet (n=37 patients).
- 2. Group 2:- Intramedullary tibia nailing without the use of a tourniquet (n=37 patients).

Tourniquet used: A single bladder pneumatic tourniquet cuff, of a size suitable for the size of the limb, was applied to the mid-thigh of the limb to be operated on. Cotton soft-roll padding was used beneath the tourniquet cuff. The tourniquet cuff, after application, was additionally wrapped with crepe bandage to prevent it from slipping. The cuff was connected to microprocessor-controlled pneumatic tourniquet device. Before the skin incision, the limb was elevated and exsanguinated using sterile Esmarch's bandage. Immediately after the exsanguination, the tourniquet pressure was elevated to 280 to 300 mm of Hg. The tourniquet timer was started at the time of inflation of the tourniquet and was stopped at the deflation of the tourniquet.

# Statistical analyses

The data on demographic parameters like age and gender was obtained for patients in two treatment arms and was expressed in terms of numbers and percentages. The mean and standard deviation of the age was also obtained. The distribution of patients as per the duration of surgery and tourniquet used was also obtained. The CPK levels of patients in both treatment arms before and after surgery were obtained and expressed in terms of mean, standard deviation, and median. The correlation of CPK levels was also obtained with the duration of surgery. The number of days for straight leg raising post-surgery and VAS (Pain score) was expressed in terms of mean, standard deviation, and median; and was compared between two groups using Multivariate ANCOVA. The significance level was set at P < .05.

## **Observations & Results**

Baseline characteristics were similar in both groups. In a group, 1 mean duration of surgery was 77.68 +/- 20.65 min and in a group, 2 was 86.03+/- 20.75 minute. The difference in the mean duration between the two groups was statistically insignificant with a P-value of 0.087 (P > 0.05).

**CPK Level:** In Group 1, the mean CPK level was 211+/71.1, while after surgery, the mean level was 903.78+/268.09. The difference between the pre and post-surgery CPK levels was significant with P-value < 0.0001. In Group 2, the mean CPK level before surgery was 191.76 +/-71.94 and post-surgery, the mean level was 389.49+/-108.04. The difference between the pre and post-surgery CPK levels was statistically significant (Table1). As regards comparing CPK levels between two arms surgery, the difference in the CPK levels of two arms was statistically significant with P-value 0.000(P < 0.05).

**SLR:** In Group 1, the mean duration for SLR was 3.41+/.599, whereas in Group 2 the mean duration of SLR was 2.51+/-.511, and the difference between two groups is statistically significant (Table1). On applying MANOVA we observed SLR is also affected by the duration of surgery, with P value .000 (P < 0.05) i.e. the mean scores in patients with duration of surgery more than 90 minutes were significantly

higher than that of mean scores in patients with duration of surgery less than 90 min (Table1).

**VAS Score:** Difference in the mean scores between two groups was statistically significant at the 2nd-4th day as indicated by P-values < 0.05. The difference was statistically insignificant on the 5th day with P-value > 0.05(Figure 1). The mean scores in patients with duration of surgery more than 90 minutes were significantly higher than that of mean scores in patients with duration of surgery less than 90 min in both groups.

#### **Discussion**

The use of tourniquet has been known for ages, however, the side effects of using tourniquet for surgical procedures had been only sparsely studied in the recent literature and that too only after the advent of total knee replacement. There has been constant confusion about whether tourniquet should be used as a routine or not. The review of the literature suggests that tourniquet used for more than 90 minutes causes postoperative complications like oedema, infection, deep vein thrombosis, the problem of wound healing and functional recovery of the quadriceps muscle [3, 12]. Keeping this in mind, we have studied the effect of a tourniquet, as indicated by Creatine Phosphokinase levels on functional recovery of muscle and joint.

We observed that levels of CPK depends on both tourniquet application and duration of the surgery. On applying MANOVA we observed that there was a threefold increase in mean CPK when the duration of surgery was less than 90 minutes while there was fivefold increase in mean CPK when surgical duration exceeded 90 minutes in tourniquet group 1 (Table2 and Figure2) but only 2 times increase in CPK in group 2, and not affected by the duration of surgery. Thereby, implying that it is much safer not to use tourniquet where surgery is going to be prolonged. The mean CPK level was also affected by velocity of trauma, as we observed that mean preop CPK score in both group was less in simple fracture where duration of surgery was less than 90 min as compared to mean preop score in high velocity trauma where duration of surgery was more than 90 min, but this increase was not statistically significant.

Looking at the primary outcome measure pain, we observed that there was a significant increase in mean pain score in group 1 as compared to group 2 between day 2 to 5 postoperatively. The difference in the mean scores between the two groups was statistically significant from 2nd to 5th postoperative day as indicated by P-values < 0.05. This difference became statistically insignificant from 6th to 7th postoperative day with P-value > 0.05. There is also a correlation between postoperative mean pain score and duration of surgery as the difference is statistically significant. Tsarouhas A *et al.* [9] observed that in arthroscopic

meniscectomy, where the duration of surgery and tourniquet time is usually less than 30 minutes, the difference in pain perception between the tourniquet and non-tourniquet group was not statistically significant, which is in contrast to our study, where we observed that that early postoperative pain was significantly less in patients who were operated without a tourniquet in comparison to the patients who were operated with tourniquets. Tai T W *et al.* and Ledin H *et al.* [10, 11] also noted similar findings in their study.

As far as the Straight Leg Raising is concerned, when the tourniquet was used the difference in the time required for straight leg raising between two duration categories (Less than 90 minutes and more than 90 minutes) was statistically significant (P < 0.05). This indicates that the return of SLR was much more delayed in patients, where the tourniquet was used for more than 90 minutes which corresponds with the findings of Li B et al., Abdel- Salem et al. [8, 12]. When the tourniquet was not used the difference in the time required for straight leg raising between two duration categories (Less than 90 minutes and more than 90 minutes) was statistically insignificant with a P-value of 0.1198 (P < 0.05). The mechanism behind the reduced range of motion is unclear. However, the postoperative thigh pain might reflect muscle injury due to physical damage, as well as reperfusion injury, which might both cause a degree of muscle fibrosis as stated by Ledin et al. [10].

We observed a significantly greater number of complications like infection, induration, and swelling in the tourniquet group. Twenty-three percent of patients in the tourniquet group developed wound infection compared with only 5.8 % of the non-tourniquet group (p < 0.05). The increased incidence of postoperative swelling and ecchymosis could be attributed to post op anoxic inflammatory oedema after prolonged tourniquet application as stated by Silver R *et al.*, Bannister GC, and Li B *et al.* [8, 13, 14].

Our study has certain limitations. First, slightly less small sample size with smaller subgroups for the various time interval could have failed to eliminate sampling errors. An a priori power analysis was performed. For a repeated-measures analysis, including between-subjects and within-subject interactions, between 2 independent groups with a minimum effect size of 0.20 and at least 2 consecutive measurements, a total sample size of 80 was calculated to have greater than 80% power to address the test hypothesis. We could recruit only 74 subjects. Second, different fracture patterns of the tibia influenced the muscle injury, duration of surgery, and the resultant postoperative outcomes, which were not accounted for in this study. Third, the surgery was performed by various surgeons who had a varying influence on soft tissue handling and resultant muscle injury.

Table 1: Primary outcomes

Group	duration	Mean	Std. Deviation	N	P-Value
CPK Preop	<90 min	179.75	68.104	20	0.92
Group 1	>90 minute	248.41	72.001	17	
CPK Preop Group 2	<90 min	154.69	61.549	16	
	>90 min	220.00	67.380	21	
CPK Postop Group1	<90 min	630.00	270.953	20	0.0001
	>90min	1240.00	253.698	17	
CPK Postop Group 2	<90min	347.50	97.946	16	
	>90min	421.48	106.460	21	
SLR group1	<90min	3.20	.523	20	0.000
	>90min	3.65	.606	17	
SLR group2	<90min	2.44	.512	16	
	>90min	2.57	.507	21	

#### Conclusion

Our study showed that tourniquet use for more than 90 minutes during tibial nailing has negative effect on postoperative pain and return of function. This tourniquetinduced muscle damage is detectable in the systemic circulation in form of raised CPK levels and significantly greater number of complications like infection, induration, and swelling in the tourniquet group.

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